



Dkt. 03129CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Group Art Unit: 1616
CHANTAL AMALRIC et al Examiner: M. Lamm
Serial No.: 10/635,898
Filed: August 7, 2003
For: NOVEL TOPICAL COMPOSITIONS WITH AN OILY OUTER PHASE AND
PROCESS FOR THEIR PREPARATION

DECLARATION OF CHANTAL AMALRIC UNDER 37 CFR § 1.132

Honorable Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Chantal AMALRIC, do hereby declare as follows:

I am a named inventor of the above-identified patent application.

I am a pharmacist by training and also highly experienced in cosmetic formulation. I have been working in the cosmetics industry since 1984 and I have been working for the assignee in the above-identified application, Seppic, as manager of the applied cosmetics research team since 1989. During this period I have contributed to 26 patents filed mostly in France, with regular extension to the rest of Europe and the United States.

CA
I am familiar with the Office Actions received during the prosecution the above-identified patent application, and I am familiar with the English language and am specifically aware of the contents of the outstanding Final Office Action dated April 1, 2005.

The present patent application discloses and claims topical sunscreen compositions, these compositions comprising a three-phase emulsion with two aqueous inner phases, one of which is an aqueous gel, and an oily external phase. At least one of the three separate phases contains a sunscreen filter.

As specified on page 7, lines 29 to 32 of the present application, the aqueous gel that constitutes one of the two inner aqueous phases is obtained by gelling an aqueous phase with a polymer.

As indicated on page 8, lines 9 to 10, the aqueous gel in the context of the present application must have a viscosity of greater than 2000 cPs (2000 centipoise, also referred to in the art as 2000 mPa.s, where 1 cPs = 1 mPa.s), and preferably greater than 20 000 cPs, these values being widely accepted by practitioners in the cosmetics and polymer fields in general.

The present application currently includes two independent claims, these being claim 19 directed to the topical sunscreen compositions themselves and claim 29 directed to a process for their manufacture.

In the Final Office Action, it was alleged that claims 19-21, 24-26, 28, 29, 33 and 36-39 were anticipated under 35 USC § 102 by Briggs et al, claims 27, 30-32 and 34-37 were obvious under 35 USC § 103 over Briggs et al, and claims 22-23 were obvious under 35 USC § 103 over Briggs et al in view of Milius et al (WO 00/56438 as translated by US 6,488,946), or in view of Ansmann (US 5,840,943).

In section 7 of the Final Office Action, it was stated that: "With respect to xanthan gum, since phase L (xanthan gum and propylene glycol) is added together with phase K (deionised water) in Example IV, it is reasonable to conclude that the both phases will mix and form an aqueous gel. Since the Office does not have the facilities for examining and comparing applicants' products with the product of the prior art, the burden is on

applicant to show novel and unobvious differences between the claimed product and the product of the prior art (i.e., that the multiple emulsion of the prior art does not possess the same material and functional characteristics of the claimed emulsion)."

In order to make the requested comparison, we have now, in our laboratories and under my supervision, reproduced the examples given in the Briggs reference, using an experimental protocol and available products exactly equivalent to those given by Briggs.

In particular, we measured the viscosities of all the aqueous (or, in the case of phase L, alcoholic) phases of the examples of the Briggs reference, i.e. phases H, I, J, K and L and combinations of these phases.

The viscosities were measured with the exact quantities of products given in the Briggs reference, all substances therefore being at the concentrations given in the reference. The source of polyvinylpyrrolidone used was the product sold under the name Luviskol® K17, which is exactly the same grade as that used in the Briggs reference. Viscosity measurements were carried out with a Brookfield viscometer at 20°C and 6 rpm. Example IV is the only experimental example of the Briggs reference containing a hydrophilic polymer (xanthan gum) that is suggested in the reference (page 15) to be a gelling agent (xanthan gum). Our results for the aqueous (or hydrophilic) phases of example IV are as follows:

Phase (or mixture of phases)	Viscosity (cPs)	Observations
H	< 50	-
I	< 50	-
H + I	< 50	-
J	< 50	-
K	-	(there are no ingredients in phase K of example IV)
L	60	a xanthan gum deposit is also observed
J + K + L	200	-
H+I+J+K+L	< 50	-

By way of comparison, the aqueous gels in the phases used in the experimental Examples of the present application show viscosities of 80,000 cPs (Example 1) and 70,000 cPs (Example 2), which are characteristic of "gels", in the way this term is understood in the cosmetics field.

Returning to the above-mentioned citation from the outstanding Office Action, it was alleged that in example IV of the Briggs reference, phase L containing xanthan gum and propylene glycol would combine with the deionized water of phase K to give an aqueous gel. However, in example IV of the Briggs reference, phase K contains no water (0% is indicated, page 20, last line).

Further, even when phase L is mixed with further aqueous phases, no viscosity approaching the minimum of 2000 cPs for a "gel" is observed. In this context, it is appropriate to note that in the experimental section of Briggs, the reference says (third paragraph of page 22) "Finally, phases K, L, M and N are added as diluent" (emphasis added). As a professional formulator of cosmetic compositions, it is my opinion that when a phase (such as phase L, or combinations of phases including phase L) is said to be a "diluent", this certainly does not suggest that it is a viscous material, but on the contrary clearly indicates that

it is a non-viscous material. I also carried out in my laboratory preparations of other examples of the Briggs reference, examples I, II, III, V and VI. Example VII could not be reproduced because we were not in possession of the azelaic acid needed for phase H. I carried out these experiments in order to determine whether the polyvinylpyrrolidone (Luviskol® K17), in the amounts in which it is used in these examples, is able to create viscous aqueous phases. However, in every case, the observed viscosity was less than 50 cPs, with exception of 140 cPs for phase J (alone) of example V. There is no reason to believe, in view of the amounts of polyvinylpyrrolidone used in example VII, that this example would give rise to any greater viscosity than the other examples which I tested.

Furthermore, we tested "aloe vera gel", which is mentioned in phase N of Example III. However, we found that this is a relatively fluid material, despite its name of "gel", and its viscosity was less than 50 cPs. Even in combination with other aqueous phases (H, I, J) of example III, no material with a viscosity approaching 2000 cPs could be obtained.

Therefore, I am confident in stating that none of the aqueous phases of any of the experimental examples of the Briggs reference give rise to an "aqueous gel", according to the meaning which a cosmetic scientist would normally attribute to this term.

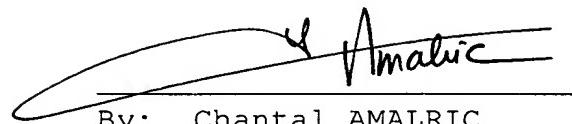
Based on the above-reported tests of compositions disclosed in the Briggs et al reference, it is my opinion that there is no reason to believe that Briggs et al teaches an emulsion having two internal aqueous phase in which (only) one of the internal aqueous phases is a gel.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may

jeopardize the validity of the application or any patent issued thereon.

0 19/9/2005

Date



By: Chantal AMALRIC